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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

6

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/975,853	AMDAHL, MICHAEL J.
	Examiner	Art Unit
	Cheyne D Ly	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 February 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

1. The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.
2. Claims 1-15 are examined on the merits.

OBJECTIONS

3. The abstract of the disclosure is objected to because it contains the abbreviation of "PTH". Correction is required. See MPEP § 608.01(b).

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Specific to claim 1, lines 2 and 4; claim 5, line 1; claim 7, line 1; claim 9, line 1; claim 10, line 2; and claim 11, line 3, Applicant uses the abbreviations of "PTH" or "bPTH". Abbreviations in claims are vague and indefinite unless accompanied by the full name, usually in parentheses.
7. Claim 2 recites the limitation "linear model" in line 1. There is insufficient antecedent basis for this limitation in the claim.
8. Specific to claims 5, line 1; claim 9, line 1; claim 10, line 2; and claim 11, line 3, the term "bPTH/80" causes the claims to be vague and indefinite because it is unclear whether the

baseline PTH value is being divided by 80 or the bPTH value is equal to 80. Clarifications of the metes and bounds of the claims is required.

9. Specific to claim 7, line 1, claim 10, line 1, and claim 13, line 1, Applicants use the abbreviations of “ESRD”. Abbreviations in claims are vague and indefinite unless accompanied by the full name, usually in parentheses. Claims 8, 9, 11, 12, 14, 15 are rejected for being directly or indirectly dependent from claim 7.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cummings et al. (US 5,891,868 A).

11. Cummings et al. discloses a method for determining the initial and final doses of vitamin D compound (column 13, lines 54-65), as in claim 1, steps b) and d).

12. The method of Cummings et al. comprises measuring the baseline level of PTH (column 16, lines 24-29), as in claim 1, step a).

13. The hormone and vitamin levels were analyzed using a logistic model (column 10, lines 51-60). Using a general linear model, a correlation is established between baseline PTH and vitamin D dosage (column 10, lines 66-67 and Table 2). A linear regression analysis is performed on hormone levels and other contributing factors to bone loss (column 17, lines 10-12), claims 1, step (c).

14. Cummings et al. discloses the use of logistic models, linear regression analysis, developed by SAS Institute, Cary, N.C., to analyze the relationship between predictors and bone loss (column 3, lines 45-51). A reference by the SAS Institute is not used as prior art but only to disclose that the logistic models from the SAS Institute include a zero intercept linear model wherein the intercept of the regression line is zero (the predicted Y value when X is 0) (SAS, page 1, line 9-13), as in instant claim 2.

15. It is noted that the Examiner has interpreted the instant claimed invention to comprise independent steps, wherein, step (c) does not depend on steps a) or b) for parameters for the regression analysis.

CLAIM REJECTIONS - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al. (US 5,891,868 A) taken with Knutson et al. (US 5,602,116 A).

18. Cummings et al. discloses the limitations of claims 1 and 2 as discussed above. However, Cummings et al. does not disclose the limitations of administering vitamin D₂, ESRD and bPTH/80.

19. Knutson et al. discloses a method for treating secondary hyperparathyroidism by administering sufficient vitamin D₂ (Abstract etc.), as in claim 13. The preferred drug is 1 α , 25-

dihydroxyvitamin D₂, generically known as paricalcitol (instant specification, page 2, lines 6-7), as in claims 3, 4 and 6.

20. The baseline serum PTH (bPTH) is 480, which is divisible by 80 (column 11, line 9), as in claims 5 and 9-11.

21. The method of Knutson et al. comprises administering to about 100 μ g of vitamin D₂ (claim 3) to end stage renal disease patients with elevated PTH (column 5, lines 1-7), as in claims 7, 8, and 12-15.

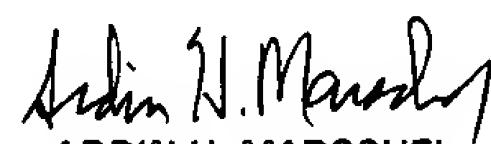
22. Cummings et al. discloses that low serum level of vitamin D compounds leads to bone loss disorders (column 2, lines 43-45) due to calcium imbalance. Knutson et al. discloses that vitamin D compounds would be useful in restoring calcium balance (column 1, lines 56-58), thus, suggesting a treatment for bone loss disorders. Further, Knutson et al. discloses osteoporotic patients are orally administered vitamin D₂ compound, blood and urine chemistries are monitored, results in higher serum calcium in subjects, and bone mineral density increases with vitamin D₂ treatments and decreases with placebo treatment (columns 8-9, Example 2).

23. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept of low serum levels of vitamin D compounds lead to bone loss disorders (column 2, lines 43-45) as taught by Cummings et al. and treating patients with bone loss disorders with an increasing dosage (1 μ g/day to 4 μ g/day) of vitamin D₂ to increase bone density (columns 8-9, Example 2), as taught by Knutson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of Cummings et al. to treat patients with bone loss and administer to the said patient with effective amount of vitamin D₂, as taught by Knutson et al.

CONCLUSION

24. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.
25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.
27. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
7/29/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER